

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: December 10, 2014

PROJECT ANALYST: Jane Rhoe-Jones

TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: Q-10336-14 / Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Pamlico / Add six dialysis stations to existing facility for a facility total of 31 stations upon project completion / Beaufort County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Pamlico is currently certified for 25 in-center dialysis stations, provides in-center hemodialysis and training and support for both peritoneal dialysis (PD) and home hemodialysis (HH). In this application, the applicant proposes to add six in-center dialysis stations to the existing facility for a facility total of 31 in-center dialysis stations upon completion of this project.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2014 State Medical Facilities Plan (2014 SMFP). The SMFP provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2014 SDR, the county need methodology shows there is no need for any additional dialysis stations in Beaufort County. However, an applicant is eligible to apply for additional dialysis

stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The July 2014 Semiannual Dialysis report (SDR) reports that as of December 31, 2013 there were 25 certified dialysis stations at FMC Pamlico and 85 in-center patients, which is an 85% utilization rate or 3.4 patients per station [85 patients / 25 certified stations = 3.40; 3.40 / 4 = 0.8500]. In this application, FMC Pamlico is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate is 3.4 patients per station, or 85%, as calculated above.

See the following table, which illustrates the facility need methodology:

OCTOBER 1 REVIEW - JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/13		85.0%
Certified Stations		25
Pending Stations		0
Total Existing and Pending Stations		25
In-Center Patients as of 12/31/13 (SDR2)		85
In-Center Patients as of 6/30/13 (SDR1)		79
Step	Description	
	Difference (SDR2 - SDR1)	6
(i)	Multiply the difference by 2 for the projected net in-center change	12
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/13	0.1519
(ii)	Divide the result of Step (i) by 12	0.0127
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/12 until 12/31/13)	0.1519
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	97.9114
(v)	Divide the result of Step (iv) by 3.2 patients per station	30.5973
	and subtract the number of certified and pending stations as recorded in SDR2 {25} to determine the number of stations needed	6

Step (C) of the facility need methodology (2014 SMFP, page 364) states, “The facility may apply to expand to meet the need established, [...] up to a maximum of ten stations.” As shown in the table above, based on the facility need methodology for dialysis stations, the FMC Pamlico facility has a need for six additional stations. The applicant proposes to add six new stations and therefore, the application is consistent with the facility need methodology for dialysis stations. Thus, at the completion of this proposed project, FMC Pamlico will be certified for 31 in-center dialysis stations.

Policies

There is one policy in the 2014 SMFP that is applicable to this review: Policy GEN-3. Policy GEN-3 states:

“A CON applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan (SMFP) shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A CON applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A CON applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the SMFP as well as addressing the needs of all residents in the proposed service area.”

The applicant addresses Policy Gen-3 in Section I.13, pages 4-8, Section II.1, pages 19-22, Section II.3, pages 26-29, Section V.7, page 43, and Section VI, pages 44-48.

Promote Safety and Quality

In Section I.13, pages 4-8, the applicant describes its corporate structure and how that structure contributes to the provision of quality dialysis services, specifically its Clinical Services Department, Technical Services Department, Regulatory Affairs and Law Departments as discussed below:

- Clinical Services Department
 - Serves as a clinical resource for the entire FMC network
 - Provides facilities with the best procedures and equipment available
 - Assists facility managers and medical personnel with questions and concerns on clinical operations
 - Provides ongoing Clinical Review Program, guidelines for comprehensive training, and Quality Assurance Program
- Technical Services Department
 - Oversees the technical and mechanical aspects of dialysis
 - Supported by a research and quality control team that leads the industry in dealing with technically complex issues facing dialysis providers
- Regulatory Affairs and Law Departments
 - Deals with legal and regulatory issues

- Provides interpretation of legislation and government policy to ensure compliance
- Other Management Resources, including but not limited to:
 - Health, Safety and Risk Management - provides safety and risk management services to each facility
 - Research – The Renal Research Institute involves dialysis facilities with strong ties to academic research institutions to ensure that all BMA dialysis facilities utilize the latest technology to deliver quality dialysis services to its patients.
 - Regional Vice Presidents – provide operational direction and monitoring of daily operations

In addition, in Section II.3, pages 26-27, the applicant describes the programs currently in place for staff training and orientation, such as a 10-week training program for each new employee. In Exhibit 9 the applicant provides a copy of the *Core Curriculum for the Dialysis Technician*.

Additionally, in Exhibit 8, the applicant provides a copy of Fresenius Medical Care's (FMC) corporate *Quality Assessment and Performance Improvement for FMS Inpatient Services Programs*, which details FMC's procedures regarding safety and quality in its dialysis facilities. In Section II.1, pages 19-20, the applicant describes the *UltraCare*® certification which all BMA facilities are urged to attain. In Section II.3, pages 28-29, the applicant describes additional corporately mandated measures for all BMA facilities to ensure the provision of quality services in its dialysis facilities.

In Section V.7, page 43, the applicant states that BMA facilities have contained operating costs while providing care and treatment to its patients. The applicant further states that the proposed project will not adversely affect quality, but will enhance the quality of life for BMA ESRD patients.

The applicant adequately demonstrates that the proposal will promote quality and safety.

Promote Equitable Access

In Section II.1, page 20, the applicant states:

“BMA has removed the economic barriers with regard to access to treatment. The overwhelming majority of dialysis treatments are covered by Medicare / Medicaid; in fact, within this application, BMA is projecting that greater than 93% of the In-Center dialysis treatments will be covered by government payors, Medicare, Medicaid or VA.

...

BMA is also keenly sensitive to the second element of 'equitable access' – time and distance barriers. At this time, Beaufort County has only one operational dialysis facility: FMC Pamlico. As the dialysis patient population of Beaufort County and surrounding continues to increase, the need for dialysis stations will continue to increase. BMA notes that the July 2014 SDR indicates that Beaufort County has a three station deficit; BMA is applying in this application to add six dialysis stations to FMC Pamlico. The addition of these stations at FMC Pamlico will better serve the ESRD patient population of that area."

Also in Section VI.1, page 44, the applicant states that BMA has a long history of providing dialysis services to the underserved populations in North Carolina. The applicant states that in North Carolina BMA facilities in FY 2013, Medicare represented 83.97% of dialysis treatments, and Medicaid represented an additional 4.82% of treatments.

The applicant provides a table on page 44 and illustrated below of the patient mix of FMC Pamlico:

FACILITY	MEDICAID/ LOW INCOME	ELDERLY (65 +)	MEDICARE	WOMEN	RACIAL MINORITIES
FMC Pamlico	5.6%	19.6%	88.8%	3468%	69.2%

The applicant adequately demonstrates that the proposal will promote equitable access to dialysis services in Beaufort County.

Maximize Healthcare Value

In Section II.1, page 21, the applicant states:

"BMA is projecting a capital expenditure of \$16,500 for this project. BMA is not seeking State or Federal monies to develop the CON application, or the addition of these stations at the FMC Pamlico facility; BMA is not seeking charitable contributions. Rather, BMA, through its parent company, FMC is taking on the burden to complete this addition of stations in an effort to ensure sufficient capacity for the growing patient population utilizing FMC Pamlico. As an additional consideration, BMA notes that the overwhelming majority of dialysis treatments are reimbursed through Medicare, Medicaid, or other government payor sources. For example, within this application, BMA projects that 93% of the in-center treatments are projected to be reimbursed by government payors. The point here is that government payors are working from a fixed payment schedule, often at significantly lower reimbursement rates than the posted charges. As a consequence BMA must work diligently to control costs of delivery for dialysis."

The applicant adequately demonstrates that the proposal will maximize healthcare value.

Conclusion

In summary, the applicant demonstrates that its proposal to develop six additional hemodialysis stations at FMC Pamlico is consistent with *Policy GEN-3: Basic Principles*. The application is also consistent with the facility need determination in the 2014 SMFP. Therefore, the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Pamlico proposes to add six in-center dialysis stations to the existing facility, pursuant to the facility need determination, for a facility total of 31 stations upon completion of this project. The July 2014 Semiannual Dialysis report (SDR) reports that as of December 31, 2013 there were 25 certified dialysis stations at FMC Pamlico and 85 in-center patients, which is an 85% utilization rate or 3.4 patients per station [85 patients / 25 certified stations = 3.40; 3.40 / 4 = 0.8500]. BMA is the only provider of dialysis services in Beaufort County.

Population to be Served

In Section III.7, pages 31-32 of the application, the applicant projects the following population for FMC Pamlico, which is based on the current patient population.

COUNTY	OPERATING YEAR 1 JAN-DEC 2016			OPERATING YEAR 2 JAN-DEC 2017			COUNTY PATIENTS AS A % OF TOTAL	
	IN-CTR.	HOME	PD	IN-CTR.	HOME	PD	YEAR 1	YEAR 2
Beaufort	98	0	13	104	0	14	92.50%	92.90%
Chowan	0	1	0	0	1	0	.83%	.80%
Hyde	4	1	0	4	1	0	4.17%	3.90%
Martin	0	1	0	0	1	0	.83	.80%
Pitt	0	1	0	0	1	0	.83	.80%
Washington	0	1	0	0	1	0	.83	.80%
Total	102	5	13	108	5	14	100.00%	100.00%

Therefore, in Operating Year One, the applicant projects to serve 102 in-center patients on 31 dialysis stations, which is 3.29 patients per station, or 82% of capacity [$102 / 31 = 3.29$; $3.29 / 4 = 0.822$]. Likewise, in Operating Year Two, the applicant projects to serve 108 in-center patients on 31 stations, which is 3.48 patients per station, or 87% of capacity [$108 / 31 = 3.48$; $3.48 / 4 = 0.870$]. Thus, in the first operating year, the applicant projects to serve at least 3.2 patients per station per day, as required by 10A NCAC 14C .2203(b).

The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

In Section III.1, page 30, the applicant states the application is filed pursuant to the Facility Need Methodology (2014 SMFP). In Section II.1, pages 12-15, and Section III.7, pages 32-35, the applicant provides the following assumptions and methodology it used to project the need for six additional stations at FMC Pamlico:

1. *“This project is scheduled to be completed December 31, 2015.*

*Operating Year 1 is the period January 1 through December 31, 2016;
Operating Year 2 is the period January 1 through December 31, 2017.*

2. *BMA does **not** assume that the in-center patient population of the facility will increase at the Beaufort County Five Year Average Annual Change Rate [emphasis in original]. Rather, BMA has evaluated the growth of the facility in-center patient population using the Facility Need Methodology. Facility Need Methodology indicates that the facility in-center census has increased at a rate of 15.2% BMA believes this rate will not likely be sustained for many years into the future. Consequently BMA will utilize a growth rate of only 6.4% This rate is twice the Beaufort County Five Year Average Annual Change Rate of 3.2%, but far less than the recently demonstrated 15.2% BMA expects growth of the facility in-center census at this rate will continue for the next several years. BMA will demonstrate growth of only those patients residing within Beaufort County.*
3. *BMA assumes that the patients residing in other counties and dialyzing at FMC Pamlico are dialyzing at FMC Pamlico as a function of patient choice. BMA will not demonstrate any increase in this segment of the patient population but does project these patients to continue dialysis at FMC Pamlico. These patients will be added to projected patient population for FMC Pamlico at appropriate points in time.”*
4. *BMA will utilize the Beaufort County Five Year Average Annual Change Rate of 3.2% to demonstrate growth of the home dialysis patient population. However, BMA will only apply the growth rate to Beaufort County residents. Patients residing in other counties are assumed to be dialyzing with the FMC Pamlico home program*

as a function of patient choice. The patients of other counties will be added to the projected patient population at appropriate points in time.

5. *BMA was not serving PD patients from other counties as of June 30, 2014. This was not by design, but rather a reflection that no PD patients from other counties had been referred to the facility, or chosen to dialyze through the facility home program. BMA does not restrict admissions based upon residence location.”*

On pages 13-14 and 33-34, the applicant provides tables, represented below, to illustrate the projected in-center, home hemodialysis and peritoneal patient populations of FMC Pamlico:

FMC PAMLICO IN-CENTER PATIENT PROJECTIONS	
<i>BMA begins with the Beaufort County patient population dialyzing at the facility as of June 30, 2014.</i>	<i>84 in-center patients</i>
<i>*BMA uses one-half of the growth rate of 6.4% to project the census forward for 6 months to December 31, 2014.</i>	<i>[84 x (.064/12x6)] + 84 = 86.7</i>
<i>BMA adds the 4 patients residing in other counties. This is the projected census for December 31, 2014 [emphasis in original].</i>	<i>86.7 + 4 = 90.7</i>
<i>BMA projects this Beaufort County patient population forward for 1 year.</i>	<i>(86.7 x .064) + 86.7 = 92.2</i>
<i>BMA adds the 4 patients residing in other counties. This is the projected certification date and beginning census: December 31, 2015 [emphasis in original].</i>	<i>92.2 + 4 = 96.2</i>
<i>BMA projects this Beaufort County patient population forward for 1 year.</i>	<i>(92.2 x .064) + 92.2 = 98</i>
<i>BMA adds the 4 patients residing in other counties. This is the projected ending census for Operating Year 1, December 31, 2016 [emphasis in original].</i>	<i>98.1 + 4 = 102.1</i>
<i>BMA projects the Beaufort County patient population forward for 12 months.</i>	<i>(98.1 x .064) + 98.1 = 104.4</i>
<i>BMA adds the 4 patients residing in other counties. This is the projected ending census for Operating Year 2, December 31, 2017 [emphasis in original].</i>	<i>104.14 + 4 = 108.4</i>

FMC PAMLICO HOME HEMODIALYSIS PATIENT PROJECTIONS	
<i>BMA begins with the Beaufort County home hemodialysis patient population dialyzing with the facility as of June 30, 2014.</i>	<i>3 patients</i>
<i>BMA uses one-half of the growth rate of 6.4% to project the census forward for 6 months to December 31, 2014.</i>	<i>[3 x (.032/12x6)] + 3 = 3.1</i>
<i>BMA adds the 5 home hemodialysis patients residing in other counties. This is the projected census for December 31, 2014 [emphasis in original].</i>	<i>3.1 + 5 = 8.1</i>
<i>BMA projects the Beaufort County patient population forward for 1 year.</i>	<i>(3.1 x .032) + 3.1 = 3.2</i>
<i>BMA adds the 5 home hemodialysis patients residing in other counties. This is the projected census for December 31, 2015 [emphasis in original].</i>	<i>3.2 + 5 = 8.2</i>
<i>BMA projects the Beaufort County patient population forward for 1 year.</i>	<i>(3.2 x .032) + 3.2 = 3.3</i>
<i>BMA adds the 5 home hemodialysis patients residing in other counties. This is the projected census for the end of Operating Year 1, December 31, 2016 [emphasis in original].</i>	<i>3.3 + 5 = 8.3</i>
<i>BMA projects the Beaufort County patient population forward for 12 months.</i>	<i>(3 x .032) + 3.3 = 3.4</i>
<i>BMA adds the 5 home hemodialysis patients residing in other counties. This is the projected ending census for Operating Year 2, December 31, 2017 [emphasis in original].</i>	<i>3.4 + 5 = 8.4</i>
FMC PAMLICO PERITONEAL DIALYSIS PATIENT PROJECTIONS	
<i>BMA begins with the Beaufort County home peritoneal dialysis patient population dialyzing with the facility as of June 30, 2014.</i>	<i>11 PD patients</i>
<i>BMA uses one-half of the growth rate of 6.4% to project the census forward for 6 months to December 31, 2014.</i>	<i>[11 x (.032/12x6)] + 11 = 11.2</i>
<i>BMA projects this Beaufort County patient population forward for 1 year. This is the projected certification date and beginning census: December 31, 2015 [emphasis in original].</i>	<i>(11.2 x .032) + 11.2 = 11.5</i>
<i>BMA projects the Beaufort County patient population forward for 1 year. This is the projected ending census for Operating Year 2, December 31, 2016 [emphasis in original].</i>	<i>(11.5 x .032) + 11.5 = 11.9</i>
<i>BMA projects the Beaufort County patient population forward for 12 months. This is the projected ending census for Operating Year 2, December 31, 2017 [emphasis in original].</i>	<i>(11.9 x .032) + 11.9 = 12.3</i>

The assumptions are based on projected growth of only Beaufort County patients, to which the applicant then added the remaining patients who currently receive dialysis services at FMC Pamlico, but who reside in a county other than Beaufort. Projected utilization is based on reasonable and supported assumptions regarding historical dialysis patient population increases, and continued growth of dialysis patients at FMC Pamlico.

Access to Services

In Section VI.1, pages 44-46, the applicant states that BMA currently operates 102 facilities in 42 North Carolina counties, all of which have a patient population that includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. The applicant projects that 88.6% of its in-center patients will be covered by Medicare or Medicaid.

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for six additional in-center dialysis stations and the extent to which all residents of the area are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

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In Section III.9, pages 35-36, the applicant describes the alternatives it considered prior to the submission of this application, which include:

- 1) Maintain the status quo: The applicant states that there is a three-station deficit in Beaufort County. Therefore, this alternative is not an option because failure to apply would not abate the station deficit in Beaufort County.
- 2) Apply for fewer than six stations: The applicant states that this alternative is not consistent with the growing patient censuses at FMC Pamlico which has resulted in high utilization rates.

In addition to noting the three station deficit in Beaufort County, the applicant states:

“The county ESRD patient population is increasing. Failure to apply potentially denies access to care for patients in need of dialysis services.”

The applicant adequately demonstrates the need for six additional dialysis stations based on the continued growth of the ESRD patient population in Beaufort County and the facility's projected utilization. The discussion regarding need and projected utilization found in Criterion (3) is incorporated herein by reference.

The application is conforming to all other applicable statutory and regulatory review criteria, and thus is approvable.

In summary, the applicant adequately demonstrates that the proposal is its least costly or most effective alternative. Consequently, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Pamlico shall materially comply with all representations made in the certificate of need application and the clarifying information received November 5, 2014. In those instances where representations conflict, the applicant shall materially comply with the last made representation.**
 - 2. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Pamlico shall develop and operate no more than six additional stations for a total of no more than 31 certified in-center dialysis stations, which shall include any home hemodialysis training and isolation stations, following completion of this project.**
 - 3. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Pamlico shall install plumbing and electrical wiring through the walls for no more than six additional dialysis stations for a total of no more than 31 dialysis stations which shall include any home hemodialysis training and isolation stations.**
 - 4. Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Pamlico shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.1, pages 52-53, the applicant projects the capital cost for FMC Pamlico will be \$16,500, which includes \$3,000 for RO water treatment equipment and \$13,500 for other equipment and furniture. In Section IX, page 56, the applicant projects no working capital (start-up and initial operating expenses) associated with the proposed project, since FMC Pamlico is currently operational.

program which provides one basic fee per dialysis treatment, is “*approximately \$240 per treatment.*” This fee ‘bundles,’ or includes all ancillary services which were previously billed separately.

The applicant projects revenues in Section X.2, page 59, and operating expenses in Section X.4, page 68, for FMC Pamlico as follows:

FMC PAMLICO		
	OPERATING YEAR 1	OPERATING YEAR 2
*Total Net Revenue	\$5,622,287	\$5,834,283
Total Operating Costs	\$4,813,773	\$4,999,639
Net Profit	\$ 808,514	\$ 834,644

*Note: There is a difference in total projected revenue for both project years on pages 59 & 68; however, the differences of a few hundred dollars do not negatively impact the applicant’s net revenue.

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable, credible and supported. See Section X.2, page 60, for the applicant’s assumptions regarding in-center revenue, and Section X.2, pages 62 and 64, for the applicant’s assumptions with regard to home revenue.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the project, and that the financial feasibility of the proposal is based on reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Pamlico proposes to add six stations to the existing facility for a total of 31 stations upon completion of the proposed project.

According to the July 2014 SDR, there is one dialysis facility in Beaufort County, FMC Pamlico. The July 2014 Semiannual Dialysis report (SDR) reports that as of December 31, 2013 there were 25 certified dialysis stations at FMC Pamlico and 85 in-center patients, which is an 85% utilization rate or 3.4 patients per station [85 patients / 25 certified stations = 3.40; 3.40 / 4 = 0.8500]. The target utilization is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility, pursuant to 10A NCAC 14C .2203(b). Therefore, according to the facility need methodology in the 2014 SMFP, FMC Pamlico is eligible to apply for six additional stations.

Upon completion of the proposed project, the facility will have 31 in-center dialysis stations serving up to 102 dialysis patients at the end of Operating Year 1, which is a utilization rate of 83% [$102 / 31 = 3.29$; $3.3 / 4 = 0.825$]. Therefore, the application is conforming to the performance standard promulgated in 10A NCAC 14C .2203.

The applicant adequately demonstrates that the proposal would not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Beaufort County. Consequently, the application is conforming to this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section VII.1, page 49, the applicant provides current and projected staffing for FMC Pamlico upon project completion, as illustrated in the following table:

FMC PAMLICO			
FULL-TIME EQUIVALENT (FTE) POSITIONS			
	CURRENT	ADD	TOTAL
RN	3.50	1.00	4.50
Tech	8.00	2.00	10.00
Clinical Manager (DON)	1.00	-	1.00
FMC Director of Operations	0.15	-	0.15
Dietician	1.00	-	1.00
Social Worker	1.00	-	1.00
Home Training Nurse	4.00	-	4.00
Chief Tech	0.50	-	0.50
Equip Tech	1.00	-	1.00
In-Service	0.30	-	0.30
Clerical	1.00	-	1.00
Total FTEs	21.45	3.00	24.45

The applicant projects a total of 24.45 FTE positions upon project completion. In Section VII.4, page 50, the applicant states it anticipates no difficulty recruiting additional staff for the facility. In Section V.4(c), page 42, the applicant states the current Medical Director for FMC Pamlico is Carney Taylor, MD. In Exhibit 21 the applicant provides a September 3, 2014 letter of support from Dr. Taylor which also indicates his willingness to continue to serve as Medical Director of the facility. The applicant adequately documents the availability of resources, including health manpower and management personnel, for provision of the proposed dialysis services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support

services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section V.1, page 39, the applicant identifies the providers of the necessary ancillary and support services for FMC Pamlico. The applicant provides further detail of the ancillary and support services in Section V, pages 40-43. In Exhibits 15, 19, 21, 25 and 26, the applicant provides documentation to support the statements regarding the provision of necessary ancillary and support services. The applicant adequately demonstrates that necessary ancillary and support services are available and will continue to be available, and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health

services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for Beaufort, Chowan, Hyde, Martin, Pitt and Washington counties and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Beaufort County	21.6%	9.8%	20.2%
Chowan County	22.7%	10.7%	20.8%
Hyde County	19.7%	10.3%	26.8%
Martin County	25.1%	12.2%	21.5%
Pitt County	16.3%	6.7%	21.3%
Washington County	17.6%	8.0%	21.6%
Statewide	16.5%	6.7%	19.7%

*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by dialysis facilities. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report. (*ESRD Network 6 2013*

*Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 1/1/2013 – 12/21/2013, page 99).*¹

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race or gender. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender do not include information on the number of elderly, handicapped, minorities or women utilizing health services.

Additionally, The United States Renal Data System, in its *2013 USRDS Annual Data Report*, pages 216-223, provides national statistics for FY 2011:

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis”*² (p. 216)

The report also provides the incidence of dialysis patients in 2011, adjusted by age, gender and race, which show that 65.4% were white, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p.218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 216). The report further states:

“In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant.” (p. 216).

The *2013 USRDS Annual Data Report* provides 2011 ESRD spending by payor, as follows:

ESRD Spending by Payor		
Payor	Spending in Billions	% of Total Spending
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
Total	\$49.2	100.0%

¹<http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

²www.usrds.org/adr.aspx

The Southeastern Kidney Council (SKC) Network 6 2013 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 101, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2013		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	65	0.4%
20-34	766	5.0%
35-44	1,498	9.7%
45-54	2,746	17.8%
55-64	4,039	26.2%
65+	6,275	40.8%
Gender		
Female	6,845	44.5%
Male	8,544	55.5%
Race		
African-American	9,559	62.1%
White/Caucasian	5,447	35.4%
Other	383	2.5%

Source: SKC Network 6. Table includes North Carolina statistics only.³

FMC Pamlico demonstrates that it currently provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section VI.6(a), page 47, the applicant states there have been no civil rights access complaints filed against any North Carolina BMA facilities in the last five years. Therefore, the application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

³<http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

C

In Section VI.1(c), page 45, the applicant provides the projected payor mix for the proposed services at FMC Pamlico, as shown below in the table. The applicant projects no change in the current payor mix for either in-center patients or home dialysis patients at FMC Pamlico.

FMC PAMLICO PROPOSED PAYOR MIX		
PAYOR SOURCE	IN-CENTER	HOME
Commercial Insurance	6.23%	7.15%
Medicare	78.83%	74.87%
Medicaid	4.36%	1.17%
VA	4.81%	0.00%
Medicare/ Commercial	5.43%	16.81%
Self/Indigent	0.34%	0.00%
Total	100.00%	100.00%

The applicant demonstrates that medically underserved populations would have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section VI.5(a), page 47, the applicant states:

“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FMC Pamlico will have an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms.”

The applicant adequately demonstrates that FMC Pamlico will continue to offer a range of means by which a person can access its services. Therefore, the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section V.3, page 41, the applicant states:

“All health related education and training programs are welcomed [sic] to visit the facility, receive instruction and observe the operation of the unit while patients are receiving treatment.”

In Exhibit 19, the applicant provides an August 27, 2014 letter from FMC to the Director of the nursing program at East Carolina University, requesting to include FMC Pamlico in its clinical rotation schedule for student nurses.

The application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Pamlico proposes to add six new dialysis stations to its existing facility for a total of 31 stations upon project completion. The applicant is applying for additional stations based on the facility need methodology.

According to the July 2014 SDR, there is one dialysis facilities in Beaufort County, FMC Pamlico. The July 2014 Semiannual Dialysis report (SDR) reports that as of December 31, 2013 there were 25 certified dialysis stations at FMC Pamlico and 85 in-center patients, which is an 85% utilization rate or 3.4 patients per station [85 patients / 25 certified stations = 3.40; $3.40 / 4 = 0.8500$]. The target utilization is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility, pursuant to 10A NCAC 14C .2203(b). Therefore, according to the facility need methodology in the 2014 SMFP, FMC Pamlico is eligible to apply for six additional stations.

Upon completion of the proposed project, the facility will have 31 in-center dialysis stations serving up to 102 dialysis patients at the end of Operating Year 1, which is a utilization rate of 83% [$102 / 31 = 3.29$; $3.3 / 4 = 0.825$]. Therefore, the application is conforming to the performance standard promulgated in 10A NCAC 14C .2203.

In Section V.7, page 43, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access to dialysis services. The applicant states its proposal to add six dialysis stations will not adversely affect quality, but rather, enhance the quality of life for the ESRD patients. The applicant further states:

“... BMA facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments. In this application, BMA projects that greater than 88% of the in-center patients will be relying upon either Medicare or Medicaid. The facility must capitalize upon every opportunity for efficiency.”

See Sections II, III, V, VI and VII. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that adding six dialysis stations to the existing FMC Pamlico dialysis facility will have a positive impact on quality and access to the proposed dialysis service based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need, based on the facility need methodology, to add six dialysis stations for a total of 31 certified dialysis stations at FMC Pamlico upon completion of the proposed project.
- The applicant has and will continue to provide quality services. The information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R., Section 494 (formerly 405.2100). The information regarding ancillary and support services and coordination of services with the existing health care system in Sections V.1, V.2, V.4, V.5 (pages 39-42), and VII.2 (page 50), and referenced exhibits is reasonable and credible and demonstrates the provision of quality care.
- The applicant has and will continue to provide adequate access to medically underserved populations. In Section VI.1, page 44, the applicant states:

“It is clear that BMA provides service to historically underserved populations. It is BMA policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”

The applicant provides the following table to demonstrate that medically underserved populations will continue to have adequate access to dialysis services provided by FMC Pamlico, as below illustrated:

FACILITY	MEDICAID/ LOW INCOME	ELDERLY (65+)	MEDICARE	WOMEN	RACIAL MINORITIES
FMC Pamlico	5.6%	19.6%	88.8%	34.6%	69.2%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 88.9% of facility treatment reimbursement is from Medicare.

The applicant states in Section VI.1(a), page 44, that BMA will continue to provide dialysis services to all segments of the population, regardless of race, ethnicity, ability to pay, gender, or other considerations that would indicate an underserved status.

Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

The applicant currently provides dialysis services at FMC Pamlico. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, FMC Pamlico has operated in compliance with all Medicare Conditions of Participation within the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The proposal is conforming to all applicable Criteria

and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific findings are discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

(a) An applicant that proposes to increase dialysis stations in an existing certified facility or relocate stations must provide the following information:

(1) Utilization rates;

-C- In Section II.1, page 10, the applicant provides the utilization rate of 85.0% with 3.4 patients per station ($85 / 25 = 3.4$) as reported in the July 2014 SDR for December 31, 2013.

(2) Mortality rates;

-C- In Section II.1, page 10, the applicant provides the mortality rates as 14.1%, 23.1% and 16.6% for 2011, 2012 and 2013, respectively.

(3) The number of patients that are home trained and the number of patients on home dialysis;

-C- In Section II.3, page 10, the applicant states, “*FMC Pamlico currently has 19 patients who are home trained and dialyzing at home. Eight of the patients are home hemodialysis patients and 11 patients are peritoneal dialysis patients.*”

(4) The number of transplants performed or referred;

-C- In Section II.1, page 10, the applicant states FMC Pamlico referred 81 transplants in 2012 and 85 in 2013. Two transplants were performed in 2012 and six in 2013.

(5) The number of patients currently on the transplant waiting list;

-C- In Section II.1, page 10, the applicant states, “*FMC Pamlico has 15 patients on the transplant waiting list.*”

(6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;

- C- In Section II.1, page 10, the applicant states that there were 261 hospital admissions in 2013, 85 were dialysis related and 176 were non-dialysis related.
- (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*
- C- In Section II.1, page 11, the applicant states that there were no patients at the facility in 2012 or 2013 with an infectious disease; nor were there any conversions to infectious status during the last calendar year.

(b) An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:

(1) For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.

-NA- FMC Pamlico is an existing facility. However, the applicant provides a copy of the hospital affiliation agreement with Pitt County Memorial Hospital in Exhibit 25.

(2) For new facilities, a letter of intent to sign a written agreement or a written agreement with transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:

- (A) timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) composition of the assessment/evaluation team at the transplant center,*
- (C) method for periodic re-evaluation,*
- (D) criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
- (E) signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-NA- FMC Pamlico is an existing facility. However, the applicant provides a copy of a transplantation agreement with Pitt County Memorial Hospital in Exhibit 26.

(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-NA- FMC Pamlico is an existing facility.

(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

-NA- FMC Pamlico is an existing facility. However, in Exhibit 12 the applicant provides a copy of the *Emergency Management and Disaster Planning* policy, which provides procedures for back-up electrical service in the event of a power outage for FMC Pamlico.

(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*

-NA- FMC Pamlico is an existing facility.

(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*

-C- In Section II.1, page 12, the applicant states, “*BMA will provide all services approved by the Certificate of Need in conformity with applicable laws and regulations. BMA staffing consistently meets CMS and State guidelines for dialysis staffing. Fire safety equipment, the physical environment, water supply and other relevant health and safety equipment will be appropriately installed and maintained at FMC Pamlico.*”

(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- In Section II.1, pages 12-15, and Section III.7, pages 31-35, the applicant provides the methodology and assumptions to project patient origin as presented in the following table:

COUNTY	OPERATING YEAR 1 JAN-DEC 2016			OPERATING YEAR 2 JAN-DEC 2017			COUNTY PATIENTS AS A % OF TOTAL	
	IN-CTR.	HOME	PD	IN-CTR.	HOME	PD	YEAR 1	YEAR 2
Beaufort	98	0	13	104	0	14	92.50%	92.90%
Chowan	0	1	0	0	1	0	.83%	.80%
Hyde	4	1	0	4	1	0	4.17%	3.90%
Martin	0	1	0	0	1	0	.83	.80%
Washington	0	1	0	0	1	0	.83	.80%
Pitt	0	1	0	0	1	0	.83	.80%
Total	102	5	13	108	4.6	14	100.00%	100.00%

The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-NA- FMC Pamlico is an existing facility.

(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*

-C- In Section II.1(9), page 15, the applicant states, “*BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*”

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station*

per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

-NA- FMC Pamlico is an existing facility.

(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

-C- FMC Pamlico projects utilization of 3.29 patients per station per week as of the end of the first operating year (see page 16 of the application).

(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected in Section II.1, pages 12-15, and Section III.7, pages 31-35.

10A NCAC 14C .2204 SCOPE OF SERVICES

To be approved, the applicant must demonstrate that the following services will be available:

(1) diagnostic and evaluation services;

-C- In Section II.1, page 17, the applicant states, “*Patients will be referred to Vidant Health Systems in Washington, Vidant Health Systems in Greenville, Physicians East Medical Services, or the ECU School of Medicine Family Practice in Greenville.*”

(2) maintenance dialysis;

-C- In Section II.1, page 17, the applicant states, “*The facility will provide in-center dialysis.*”

(3) accessible self-care training;

C- In Section II.1, page 17, the applicant states, “*Patients who are candidates for self-care are referred to the facility home training department.*”

- (4) *accessible follow-up program for support of patients dialyzing at home;*
- C- In Section II.1, page 17, the applicant states, “*Patients who are candidates for home dialysis will be referred to the facility home training department.*”
- (5) *x-ray services;*
- C- In Section II.1, page 17, the applicant states, “*Patients ... will be referred to Vidant Health Systems (in Washington and/or Greenville), or Physicians East Medical Services, or Eastern Radiology in Washington.*”
- (6) *laboratory services;*
- C- In Section II.1, page 17, the applicant states, “*BMA provides on site laboratory services through contract with Spectra Labs.*” See Exhibit 15 for the laboratory services agreement with Spectra Laboratories.
- (7) *blood bank services;*
- C- In Section II.1, page 17, the applicant states, “*Patients in need of blood transfusion will be referred to Vidant Health Systems in Washington.*”
- (8) *emergency care;*
- C- In Section II.1, page 17, the applicant states, “*Emergency care for patients is provided on site by BMA staff until emergency responders arrive. In the event of an adverse event while in the facility, BMA staff are appropriately trained; in addition a fully stocked ‘crash cart’ is maintained at the facility. If the patient event requires transportation to a hospital, emergency services are summoned via phone call to 911.*”
- (9) *acute dialysis in an acute care setting;*
- C- In Section II.1, page 17, the applicant states, “*Patients requiring admission to hospital [sic] will be referred to Vidant Health Systems in Greenville.*”
- (10) *vascular surgery for dialysis treatment patients;*
- C- In Section II.1, page 18, the applicant states, “*Patients will be referred to Vidant Health Systems, Greenville Surgical Specialty, LLC, or Eastern Nephrology Vascular Access Center in Greenville.*”
- (11) *transplantation services;*

-C- In Section II.1, page 18, the applicant states, “*FMC Pamlico has a transplant agreement with Vidant Health System.*” See Exhibit 26 for a copy of the transplantation agreement with Vidant Health Systems.

(12) *vocational rehabilitation counseling and services; and*

-C- In Section II.1, page 18, the applicant states, “*Patients in need of vocational rehabilitation services will be referred to the East Carolina Vocational Rehabilitation Center.*”

(13) *transportation.*

-C- In Section II.1, page 18, the applicant states, “*Transportation services are provided by Beaufort Area Transit System (BATS), Coastal Medical Transport, Tar Heel Medical Transport, or AJ Cab Service.*”

10A NCAC 14C .2205 STAFFING AND STAFF TRAINING

(a) To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 405.2100.

-C- In Section II, page 18, the applicant states that sufficient staffing for each shift is provided. In Section VII.2, page 50, BMA states that all staffing requirements will be met as stated in 42 C.F.R. Section 494 (formerly 405.2100). The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

(b) To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.

-C- In Section II.1, pages 18-19, and Section VII.5, page 50, the applicant describes the training and continuing education required for all BMA clinical employees. The applicant states that new employees are required to successfully complete a ten-week training program, and that staff training is continually updated and documented in employee records. The applicant further states that training includes dialysis techniques, safety precautions, CPR, corporate policies and procedures. Exhibit 9 contains an outline of the training program and Exhibit 10 contains the outline of the continuing education programs.